Monomers and Polymers
Hazard communication under REACH

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Issue

Polymers are exempted from registration under the EU REACH Regulation. However, the monomer(s) and any other chemically bound substance(s) have to be registered. Following the judgment, two issues have been considered by the CEFIC Polymer Working Group (PWG):

1. How to deal with residual, unreacted monomer(s) i.e. whether they need to be considered in the Registration process;
2. The life cycle of a monomer with regard to the Chemical Safety Assessment (CSA), Chemical Safety Report (CSR) and Exposure Scenarios (ES) and the communication of safe use of the polymer with residual monomers during its life cycle.

Introduction

Recently a court case of four chemical companies against the UK Department for the Environment, Food and Rural Affairs (DEFRA) (who has policy lead for REACH in the UK) came to a conclusion on the interpretation and validity of the REACH Regulation concerning the registration of monomers. The full document can be found at: http://curia.europa.eu/jcms/jcms/j_6/, , Case C-558/07.

This paper presents the final conclusions of the CEFIC Polymers Working Group (PWG) on the opinion of Advocate General J. Kokott, delivered on 10 March 2009, taking into account the Judgment of the Court (Grand Chamber) on 7 July 2009.

Observations and conclusions

Observations

The judgment rules that the duty to register monomers relates only to the monomer which is reacted and integrated into the polymer.

Conclusions

(a) As a consequence of the judgment, unreacted residual monomers in a polymer are not part of the monomer registration process;

(b) Unreacted/residual monomers are regarded as impurities in the polymeric substance;

(c) As there is no registration obligation for polymers, there is no CSA/CSR/ES for the polymer and thus there is no formal need for an evaluation of the monomer as impurities. For purposes of hazard communication and especially when the impurity is a CMR and/or a PBT and present at > 0.1 % a hazard assessment for the impurities need to be performed;

(d) As unreacted monomers are to be regarded as impurities and excluded from the 2% and 1 tpa rules, they need not be critically addressed in the CSA, CSR and ES of the monomer used for polymerisation;

(e) For a monomer manufactured in the EU or imported as a free monomer substance into the EU, a CSA/CSR/ES for REACH registration needs to be conducted, but only covering the period of its synthesis until the polymerisation reaction;

(f) Monomers registered solely because they are imported in combined polymeric form do not require an in-depth exposure and risk assessment to be carried out in the CSA/CSR relating to the bound monomers for the submission. Residual, unreacted monomers are impurities in polymers and can be excluded from the 2% and 1 tpa rules and therefore need not be critically addressed in the CSA, CSR and ES;

(g) The CSA/CSR/ES of the monomer may only cover the uses of the monomer up until the polymerisation step;

(h) Although for REACH registration CSA/CSR/ES for a monomer stops with the polymerisation step, for residual monomer, as well as for monomers possibly formed during degradation of the polymer, a hazard assessment needs to be performed and the results communicated not as part of the ES of the monomer, but included in the main body of the SDS of the polymer;

(i) Certain parts of the ECHA guidance are now over-ruled and need not be taken into consideration.

Discussion

The conclusions of the PWG are supported by the following text in the court's judgment

Pre-judgment introduction	The Grand Chamber includes Advocate General J Kokott as a key member.
Point 24	The definition of polymer given in Article 3(5) of the REACH Regulation set out in paragraph 21 of the present judgment, registration concerns reacted monomer substances.
Point 27	It follows that the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are incorporated in polymers.
Point 34	It follows that it is not polymers which are affected by the registration obligation but only monomer substances with their own characteristics as they existed before polymerisation.
Point 36	The obligation to register monomer substances is designed to protect human health and the environment since those substances have inherent characteristics liable to have an adverse effect on them.
Point 38	It follows from all of the foregoing that the answer to the first question is that the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are integrated in polymers.
Point 48	Account being taken of the finding set out in paragraph 38 of the present judgment, reacted monomers which are constituents of polymers are subject to that obligation, whereas polymers are exempted.
Final Ruling	**The concept of 'monomer substances' in Article 6(3)** of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC **relates only to reacted monomers which are integrated in polymers.** *(emphasis added)*

Due to the points in the table above, the PWG considers the conclusions reached by the Group are valid. Also as Advocate General J Kokott is a part of the Grand Chamber it follows that her opinion was endorsed and so according to para 48 of the opinion, the life cycle of a monomer ends when it is reacted into a polymer. Indirectly, the ending of a monomer's lifecycle in the polymerisation process is confirmed by the Guidance for Monomers and Polymers: "Monomers are by definition intermediates. Therefore, they cannot be subject to authorisation under REACH for the use as monomers in polymerisation reactions." Even if a monomer is a CMR or a PBT, but because it ends its life in the polymerisation process, going through the authorisation process doesn't make sense. The PWG fully supports this concept. Any adventitious residual monomer shall be considered an impurity and should be treated as such.

Furthermore, the judgment consistently refers to the "obligation to register REACTED monomers" and this is also the main ruling (ruling 1). Hence, there is no requirement to register unreacted monomers, unless they constitute a substance in their own right.

The ruling does not clearly discuss the uses of the monomer. However, as monomer units cannot have an identified use, only the original monomer substances as they existed before

polymerisation can, and it is in this form alone that the registration requirements apply to them. Hence, the only identified use of a monomer is polymerisation. It can therefore be concluded that the use descriptor system does not apply to polymers or the reacted monomers. The Sectors of Use (SU), Product Categories (PC), Process Categories (PROC) and Environmental Release Categories (ERCs) are only relevant for the monomers up to the point of polymerisation.

If a monomer is manufactured in the EU, the registration is the same as for any other type of non-polymeric substance. The life cycle of a monomer may for example end in a chemical reaction, i.e. it is used as an intermediate. It is clear that for registration purposes, monomers are not to be treated as intermediates (articles 17 and 18 cannot be applied to monomers), but they do end their life in a chemical reaction which of course is polymerisation. This is confirmed by point 34, where it states that the registration of monomers is about “their own characteristics as they existed before polymerisation”.

When polymerisation takes place outside the EU, there is no identified use within the EU jurisdiction. Although a CSR needs to be submitted, as there is no identified uses, chapters 9 (exposure assessment) and 10 (risk assessment) need not be addressed. However, the CLP Regulation provides “an obligation for manufacturers, importers and downstream users to classify substances and mixtures on the market” (CLP Regulation, art 1.1(b)(i)).This means that industry also has to evaluate the hazardous properties of polymers. If residual (hazardous) monomer is present or present due to breakdown of the polymer, it must be part of that evaluation. The evaluation of the hazardous properties of a monomer in the REACH registration procedure is of great advantage and the results must be used in the development of the text in the main body of the Polymer SDS. Hence, the findings of the hazard evaluation done on the monomer substance by the monomer producer or importer finally must be communicated in the supply chain by the polymer producer or importer in the main body of the Polymer SDS.

This communication has been part of the good product stewardship practice the industry has applied already since long.

Finally, the judgment has consequences for the interpretation of the monomer tonnage to be considered for registration. The ECHA Guidance for monomers and polymers § 4.2.2 states: "In accordance with condition (b) of Article 6(3), only the monomer(s) and any other substance(s) ending up in the final polymer, **whether chemically bound to the polymer or not**, and for which the corresponding tonnage as reagents makes up 1 tonne or more per year are to be considered for an eventual registration." (emphasis added). In case of imported polymers, even if the amount of residual monomer exceeds a quantity of 1 tonne per year, the residual monomer does not need to be considered as part of the registration of the ‘reacted’ monomer as the residual monomer is an impurity in the polymer. Furthermore, in the subsequent example 5 diagram, only unreacted monomers removed by "purification of the polymer" are allowed to be deducted for tonnage calculation against the 1 tpa rule.

The Polymers TF concludes that the ECHA guidance is now over-ruled by the Advocate General’s Opinion, as endorsed by the European’s Court decision, and need not be taken into consideration.